



PTO/SB/08a (08-03)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 6

Complete if Known

Application Number	10/772,074
Filing Date	November 24, 2003
First Named Inventor	John Gregory ACETI et al.
Art Unit	1743
Examiner Name	Not yet assigned
Attorney Docket Number	023095.0110N2US

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		4,627,445	12-09-1986	Garcia et al.	
		5,807,375	09-15-1998	Gross et al.	
		6,048,352	04-11-2000	Douglas et al.	
		4,057,394	11-08-1977	Genshaw	
		4,254,083	03-03-1981	Columbus	
		4,258,001	03-24-1981	Pierce et al.	
		4,321,397	03-23-1982	Nix et al.	
		4,350,762	09-21-1982	De Luca et al.	
		4,394,512	07-19-1983	Batz	
		4,418,037	11-29-1983	Katsuyama et al.	
		4,737,458	04-12-1988	Batz et al.	
		4,774,192	09-27-1988	Terminiello et al.	
		4,790,979	12-13-1988	Terminiello et al.	
		4,953,552	09-04-1990	De Marzo	
		4,966,646	10-30-1990	Zdeblick	
		5,059,394	10-22-1991	Phillips et al.	
		5,077,199	12-31-1991	Basagni et al.	
		5,094,943	03-10-1992	Siedel et al.	
		5,116,759	05-26-1992	Klainer et al.	
		5,141,868	08-25-1992	Shanks et al.	
		5,174,291	12-29-1992	Schoonen et al.	
		5,179,005	01-12-1993	Phillips et al.	
		5,183,741	02-02-1993	Arai et al.	
		5,196,302	03-23-1993	Kidwell	
		5,208,163	05-04-1993	Charlton et al.	
		5,213,966	05-25-1993	Vuorinen et al.	
		5,234,818	08-10-1993	Zimmermann et al.	
		5,251,126	10-05-1993	Kahn et al.	
		5,278,079	01-11-1994	Gubinski et al.	
		5,288,646	02-22-1994	Lundsgaard et al.	
		5,302,513	04-12-1994	Mike et al.	
		5,304,468	04-19-1994	Phillips et al.	
		5,306,623	04-26-1994	Kiser et al.	
		5,308,767	05-03-1994	Terashima	
		5,360,595	11-01-1994	Bell et al.	
		5,383,512	01-24-1995	Jarvis	
		5,451,350	09-19-1995	Macho et al.	
		5,458,140	10-17-1995	Eppstein et al.	
		5,460,777	10-24-1995	Kitajima et al.	
		5,507,288	04-16-1996	Boeker et al.	
		5,568,806	10-29-1996	Cheney, II et al.	
		5,577,499	11-26-1996	Teves	
		5,582,184	12-10-1996	Erickson et al.	
		5,591,139	01-07-1997	Un et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /EW/

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	5,636,632	06-10-1997	Bommannan et al.	
	5,658,515	08-19-1997	Lee et al.	
	5,676,850	10-14-1997	Reed et al.	
	5,680,858	10-28-1997	Hansen et al.	
	5,681,484	10-28-1997	Zanzucchi et al.	
	5,682,233	10-28-1997	Brinda	
	5,697,901	12-16-1997	Eriksson	
	5,705,018	01-06-1998	Hartley	
	5,735,273	04-07-1998	Kurnik et al.	
	5,741,211	04-21-1998	Renirie et al.	
	5,746,217	05-05-1998	Erickson et al.	
	5,771,890	06-30-1998	Tamada	
	5,801,057	09-01-1998	Smart et al.	
	5,820,570	10-13-1998	Erickson et al.	
	5,827,183	10-27-1998	Kurnik et al.	
	5,840,020	11-24-1998	Heinonen et al.	
	5,855,801	01-05-1999	Un et al.	
	5,858,194	01-12-1999	Bell	
	5,866,281	02-02-1999	Guckel et al.	
	5,879,310	03-09-1999	Sopp et al.	
	5,879,326	03-09-1999	Godshall et al.	
	5,879,367	03-09-1999	Latterell et al.	
	5,893,870	04-13-1999	Talen et al.	
	5,911,737	06-15-1999	Lee et al.	
	5,912,139	06-15-1999	IwatCI et al.	
	5,925,021	07-20-1999	Castellano et al.	
	5,928,207	07-27-1999	Pisano et al.	
	5,954,685	09-21-1999	Tierney	
	5,971,941	10-26-1999	Simons et al.	
	5,972,294	10-26-1999	Smith et al.	
	5,989,409	11-23-1999	Kurnik et al.	
	5,993,189	11-30-1999	Mueller et al.	
	6,001,067	12-14-1999	Shults et al.	
	6,010,463	01-04-2000	Lauks et al.	
	6,014,577	01-11-2000	Henning et al.	
	6,023,629	02-08-2000	Tamada	
	6,030,827	02-29-2000	Davis et al.	
	6,032,059	02-29-2000	Henning et al.	
	6,041,253	03-21-2000	Kost et al.	
	6,050,988	04-18-2000	Zuck	
	6,056,734	05-02-2000	Jacobsen et al.	
	6,059,815	05-09-2000	Lee et al.	
	6,077,660	06-20-2000	Wong et al.	
	6,080,116	06-27-2000	Erickson et al.	
	6,083,196	07-04-2000	Trautman et al.	
	6,090,790	07-18-2000	Eriksson	
	6,091,975	07-18-2000	Daddona et al.	
	6,100,107	08-08-2000	Lei et al.	
	6,102,933	08-15-2000	Lee et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /EW/

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	6,103,033	08-15-2000	Say et al.	
	6,103,197	08-15-2000	Werner et al.	
	6,106,751	08-22-2000	Talbot et al.	
	6,118,126	09-12-2000	Zanzucchi	
	6,120,676	09-19-2000	Heller et al.	
	6,123,861	09-26-2000	Santini, Jr. et al.	
	6,126,899	10-03-2000	Woudenberg et al.	
	6,132,449	10-17-2000	lum et al.	
	6,142,939	11-07-2000	Eppstein et al.	
	6,175,752	01-16-2001	Say et al.	
	6,183,434	02-06-2001	Eppstein et al.	
	6,187,210	02-13-2001	lebouiz et al.	
	6,192,891	02-27-2001	Gravel et al.	
	6,200,296	03-13-2001	Dibiasi et al.	
	6,206,841	03-27-2001	Cunningham et al.	
	6,214,626	04-10-2001	Meller et al.	
	6,219,574	04-17-2001	Cormier et al.	
	6,230,051	05-08-2001	Cormier et al.	
	6,242,207	06-05-2001	Douglas et al.	
	6,245,215	06-12-2001	Douglas et al.	
	6,251,083	06-26-2001	Yum et al.	
	6,251,260	06-26-2001	Heller et al.	
	6,255,061	07-03-2001	Mori et al.	
	6,256,533	07-03-2001	Yuzhchikov et al.	
	6,272,364	08-07-2001	Kurnik	
	6,298,254	10-02-2001	Tamada	
	6,299,578	10-09-2001	Kurnik et al.	
	6,309,351	10-30-2001	Kurnik et al.	
	6,312,612	11-06-2001	Sherman et al.	
	6,322,808	11-27-2001	Trautman et al.	
	6,329,161	12-11-2001	Heller et al.	
	6,331,266	12-18-2001	Powell et al.	
	6,332,871	12-25-2001	Douglas et al.	
	6,334,856	01-01-2002	Allen et al.	
	6,350,273	02-26-2002	MinagawCi et al.	
	6,356,776	03-12-2002	Berner et al.	
	6,530,892	03-11-2003	Kelly	
	2001/0001034	05-10-2001	Douglas	
	2001/0053891	12-20-2001	Ackley	
	2002/0002326	01-03-2002	Causey, III et al.	
	2002/0002344	01-03-2002	Douglas et al.	
	2002/0004640	01-10-2002	Conn et al.	
	2002/0006355	01-17-2002	Whitson	
	2002/0016568	02-07-2002	Lebel et al.	
	2002/10020688	02-21-2002	Sherman et al.	
	2002/0136667	09-26-2002	Subramanian et al.	
	2002/0137998	09-26-2002	Smart et al.	
	2002/0160520	10-31-2002	Orloff et al.	
	2002/0177761	11-28-2002	Orloff et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /EW/

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023095.0110N2US

	4,794,926	01-1989	Munsch et al.	
	5,176,632	01-1993	Bernardi	
	5,632,410	05-1997	Moulton et al.	
	6,540,675	04-2003	Aceti et al.	
	6,923,764	08-2005	Aceti et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
		Country Code ² - Number ⁴ - Kind Code ⁵ (if known)				
		WO 97/43962 (WIPO)	11-27-1997	Mercury Diagnostics, Inc.		
		WO 97/15227 (WIPO)	05-01-1997	Medtronic, Inc.		
		WO 97/29847 (WIPO)	08-21-1997	Selfcare, Inc.		
		WO 98/31275 (WIPO)	07-23-1998	Carpe Diem Salud, S.L.		
		WO 00/14269 (WIPO)	03-16-2000	Amira Medical		
		WO 00/14535 (WIPO)	03-16-2000	Amira Medical		
		WO 00/18449 (WIPO)	04-06-2000	MiniMed, Inc.		
		WO 00/78208 (WIPO)	12-28-2000	Spectrx, Inc.		
		WO 01/16575 (WIPO)	03-08-2001	M-Biotech, Inc.		
		WO 01/52727 (WIPO)	07-26-2001	MiniMed, Inc.		
		WO 01/64105 (WIPO)	09-07-2001	Inverness Medical Technology, Inc.		
		WO 01/80728 (WIPO)	11-01-2001	Simons, Hans- Jürgen		
		WO 01/91634 (WIPO)	12-06-2001	Abbott Laboratories		
		WO 02/49507 (WIPO)	06-27-2002	Inverness Medical Limited		
		WO 02/49509 (WIPO)	06-27-2002	Insulet Corporation		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		The Diabetes Control and Complications Trial Research Group, "The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus," New Engl. J. Med. 1993; 329:977-986.	
		S. Coster et al., "Monitoring blood glucose control in diabetes mellitus: a systematic review," Health Technology Assessment (12) 2000.	
		W.H. Smart et al., "The use of silicon microfabrication technology in painless glucose monitoring," Diabetes Technology & Therapeutics 2:4, 549(2000).	
		M. Beregszaszi et al., "Nocturnal hypoglycemia in children and adolescents with insulin-dependent diabetes mellitus: prevalence and risk factors," J. Pediatr. 1997 Jul; 131 (1 Pt.1): 27-33.	
		H.P. Chase, "Continuous subcutaneous glucose monitoring in children with type 1 diabetes," Pediatrics 2001 Feb; 107(2):222-6.	
		Andrew Spielman, "Mosquito - A natural history of our most persistent and deadly foe," Sc. D., Hyperion.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /EW/

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023095.0110N2US

	Su Yum, "Capillary blood sampling for self-monitoring of blood glucose," Diabetes Technology & Therapeutics Vol. 1, Nov. 1, 1999.	
	P. Trinder, "Determination of glucose in blood using glucose oxidase with an alternate oxygen acceptor," 6(1969) 24.	
	O. Sonntag, dry chemistry, "Analysis with carrier-bound reagents," 1993 Elsevier Science Publishers, see p. 181.	
	ADA Self Monitoring of Blood Glucose, A Consensus Development Conference, Diabetes Care 1994:7:81-6.	
	R.N. Johnson et al., "Accuracy of devices used for self-monitoring of blood glucose," Ann. Clin. Biochem. 1998:35:68-74.	
	R.N. Johnson et al., "Analytical error of home glucose monitors: a comparison of 18 systems," Ann. Clin. Biochem. 1999:36:72-9.	
	R.N. Johnson et al., "Error detection and measurement in glucose monitors," Clin. Chim. Acta. 2001:307(1-2):61-7.	
	W.L. Clarke et al., "Evaluating clinical accuracy of systems for self-monitoring of blood glucose," Diabetes Care 1987: 10:622-8.	
	D.J. Cox. et al., "Understanding error grid analysis," Diabetes Care 1997:20:911-12	
	B. Feldman et al., "FreeStyle™: A Small-Volume Electrochemical Glucose Sensor for Home Blood Glucose Testing," Diabetes Technology and Therapeutics 2000:2(2):221-229.	
	E. Otto et al., "An intelligent diabetes software prototype: predicting blood glucose levels and recommending regimen changes," Diabetes Technology and Therapeutics 2000:2(4):569-576.	
	McGarraugh, G. et al., "Physiological influences on off-finger glucose testing," Diabetes Technology and Therapeutics 2001 Fall; 3(3):367-76.	
	Rosen, "Road to New-Age Glucose Monitoring Still Rocky," Diagnostic Insight, Summer 1999, pp.4-5, 12-13, 16.	
	Mahler et al., "Clinical Review 102 Type 2 Diabetes Mellitus: Update on Diagnosis, Pathophysiology, and Treatment," The Journal of Clinical Endocrinology and Metabolism, 84: 1165-1170, 1999.	
	McNichols et al., "Optical glucose sensing in biological fluids: an overview," Journal of Biomedical Optics, 5(1), 5-16, January 2000,	
	D'Arrigo, "GlucoWatch Monitor Poised for Approval," Diabetes Forecast, March 2000, 43-44.	
	Svedman et al., "Skin mini-erosion technique for monitoring metabolites in interstitial fluid: Its feasibility demonstrated by OGTT results in diabetic and non-diabetic subjects," Scand J Clin Lab Invest, 59(2): 115-23, April 1999.	
	Rebrin et al., "Subcutaneous glucose predicts plasma glucose independent of Insulin: Implications for continuous monitoring," Am J Physiol 277 (3 pt 1): E.561-71, Sep. 1999.	
	Collison et al., "Analytical characterization of electrochemical biosensor test strips for measurement of glucose in low volume interstitial fluid samples," Clin. Chem. 45(9):1665-73. Sep. 1999.	
	Pfohl et al., "Spot glucose measurement in epidermal interstitial fluid - an alternative to capillary blood glucose estimation?" Exp Clin Endocrinol Diabetes, 108(1):1-4, 2000.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /EW/

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		Kumetrix, Inc., "Painless blood glucose monitoring, courtesy of the mosquito," Start-Up, p. 27, December 1999.	
		"Taking the 'ouch' out of needles: arrays of 'microneedles' offer new technique for drug delivery," Science Daily, 1999.	
		integonline.com; Integ website LifeGuide Glucose Meter No lancets. No. Blood 2000.	

Examiner
Signature

/Eric Winakur/

Date
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09/28/2008

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